Historical Control Data (1992 — 1994) for Developmental and Reproductive Toxicity Studies using the Crl:CD® (SD)BR Rat

Compiled **by**

MARTA

(Middle Atlantic Reproduction and Teratology Association)

MTA

(Midwest Teratology Association)

March 1996

CHARLES RIVER LABORATORIES

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INTRODUCTION

This historical control data project is the first joint effort of MARTA, the Middle Atlantic Reproduction and Teratology Association, and MTA, the Midwest Teratology Association, to collect and summarize data from developmental toxicity and perinatal-postnatal studies conducted at laboratories of member companies. Previous MARTA projects include an abstract on Sprague-Dawley (CD) rats reproduction and spontaneous malformations (Woo and Hoar, Teratology 19: 54A,1979), an abstract on New Zealand White (NZW) rabbit reproduction and spontaneous malformations (Woo and Hoar, Teratology 25: 82A, 1982). The following summaries were distributed to the MARTA membership: CD rat and NZW rabbit reproduction in 1990, external anomalies of CD rats in 1991, and in 1993 the most recent and comprehensive project included reproduction, natural delivery, and external, visceral, and skeletal findings in CD rats and NZW rabbits from 1989 to 1992. Previous MTA projects included an abstract on CD rat, CD-1 mouse, and NZW rabbit reproduction data (Clemens, et al., Teratology 45: 485-6, 1992), an abstract on external and visceral malformations in the CD rat and NZW rabbit (Clemens, et al., Teratology 49: 388-9, 1994), and an abstract on skeletal findings in the CD rat and NZW rabbit and natural delivery data on the CD rat (Clemens, et al.. Teratology 51: 182, 1995). Summaries of the latter two projects were distributed to the MTA membership. There have been very few other comprehensive compilations of these type of data in the open literature. A list of available references for rodents and rabbits is provided in this document.

HOW THE SURVEY WAS CONDUCTED

In December, 1994 a request for data was sent to 38 companies in the US. Each company was assigned a code number. The request included a floppy disk containing five template files and instructions for entering data onto the disk. The files listed information for C-section, natural delivery, external alterations, visceral alterations, and skeletal alterations. Data from one study or generation was entered onto the appropriate file and was then saved using a file name containing the company code and a study number. The same study number for C-section data was also used in the files for external, visceral, and skeletal alterations, if appropriate. The fetal alterations files listed terms and requested the fetal and litter incidences (numbers and percent affected); the default value of zero was included for all alterations. Data that were considered to represent delayed or incomplete ossification were not included in the list of alterations. In addition, it was requested not to enter: I) skeletal alterations that were associated with an entered external alteration, 2) alterations of dead fetuses, and 3) studies of less than ten animals. The disks were returned to David Wise who loaded each file into a relational database (Microsoft Access 2.0). From that database queries were designed to sort and summarize the data.

ANIMAL SOURCES AND ENVIRONMENTAL CONDITIONS

The survey was able to accept data from any species, but this document summarizes data for Sprague-Dawley rats from Charles River Laboratories. Summary data from the various Charles River facilities are presented. The exact room number of the facility was not collected. Nor were there questions regarding environmental conditions, housing, feeding, or watering. Since all participating laboratories conduct GLP studies, it is assumed that conditions meet or exceed federal regulations for the care and housing of laboratory animals.

TERMINOLOGY AND GENERAL INFORMATION

The tables presented in this document list the reproduction parameters and fetal alterations as they appeared in the file templates. The terminology used for fetal alterations was derived from the 1993 MARTA glossary. If a specific alteration did not appear on the list, the respondent was asked to supply that information in a separate note so that the additional term could be included if deemed appropriate by the committee.

It should be noted that the averages and standard deviations presented in the C-section and natural delivery tables were derived from all the individual study groups, and, thus, are on a per study basis. The minimum and maximum values represent the lowest and highest group values from all the studies represented. In a particular category (e.g., all Gestation Day 20 studies), some parameters from a given study may not have had a value reported. Thus, the column for number of studies reported indicates how many studies were included for each parameter. In the fetal alteration tables, the FETAL INCIDENCE [Avg (%)] represents the average percent affected fetuses from all studies represented and was calculated as follows: total of all % (including 0%'s) divided by the total number of studies x 100.

ACKNOWLEDGMENTS

The following MARTA and MTA members participated in this historical control project: L. David Wise (Merck Research Laboratories), Judy Petrere (Warner-Lambert/Parke-Davis), William J. Bartek (Bristol-Myers Squibb), and George Clemens (Bayer). MARTA and MTA wish to express appreciation to Charles River Laboratories, Inc., especially Dr. William J. White, and Dr. Patricia L. Lang for their assistance in producing and distributing this document, and to William T. Moll (Merck & Co.) for his programming and database design.

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PARTICIPATING COMPANIES

Abbott Laboratories
Argus Research Laboratories., Inc.
Bristol-Myers Squibb, PRI, Evansville, IN
CIBA-GEIGY Corp., Summit, NJ
Du Pont Co., Haskell Labs
International Research and Development Corp.
Merck Research Laboratories
Pfizer Central Research
R.W. Johnson Pharm. Res. Inst., Raritan, NJ
R.W. Johnson Pharm. Res. Inst., Spring House, PA
Research Triangle Institute
Smith-Kline Beecham
Springborn Laboratories
Stonybrook Laboratories
Warner-Lambert/Parke-Davis

Note: Sprague Dawley® is a registered trademark of Harlan Sprague Dawley, Indianapolis, IN. SD ™ is a Harlan Sprague Dawley trademark.

MARTA / MTA

1992-1994

TABLE 1

Summary of Study Types and Routes of Administration

STUDY TYPE	NUMBER OF STUDIES	U	PO	IV	SC	IP	D	O
Seg. II / Developmental Tox.	148	7	100	17	7	0	12	5
Female Fertility	47	6	30	5	1	0	0	5
Male Fertility	40	21	15	3	0	0	0	1
Combined Fertility	22	4	15	3	0	0	0	0
Other	9	0	8	0	0	0	0	1

Summary of Vehicles Used with Various Study Types

STUDY TYPE	NUMBER OF STUDIES	None	H_2O	MC	Oil	Other
PO, Seg. 11 / Devel. Tox.	100	2	37	32	17	12
IV, Seg. II / Devel. Tox.	17	0	0	0	0	17
SC, Seg. II / Devel. Tox.	7	0	2	0	0	5
Dermal, Seg. I1 / Devel. Tox.	12	0	1	0	0	11
PO, Female Fertility	30	4	7	16	0	3
PO, Male Fertility	15	0	5	7	1	2
PO, Combined Fertility	15	0	2	8	1	4
PO, "Other" Studies	8	0	2	5	0	1

KEY

U = Untreated, PO = oral gavage, IV = intravenous injection, SC = subcutaneous injection, IP = intraperitoneal injection, D = dermal application, 0 = other, MC = methylcellulose (or equivalent)

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1992-1994

TABLE 2
CESAREAN-SECTION DATA

Average and S.D. calculated on a per study basis

All Crl:CD®(SD)BR Rat Studies

						All Wistar Rat Studies				
Total studies:			267					3		
Total mated females:			6,280		**No. of**			63		
Total pregnant females:			5,877		**Studies**			61		
	AVG	**S.D.**	**MIN**	**MAX**	**Reported**	AVG	**S.D.**	**MIN**	**MAX**	
Age on GD 0 (wks):	11.7	1.96	8	20	255	13.0	0.00	13	13	
Mated females:	23.5	6.33	10	48	267	21.0	1.73	20	23	
Pregnant females:	22.0	5.82	8	45	267	20.3	1.53	19	22	
% **Pregnant** of **mated:**	93.8	7.68	57	100	267	96.9	2.71	95	100	
No. **females all resorbed:**	0.05	0.21	0	1	210	0	0	0	0	
% **Pregnant all resorbed:**	0.61	6.50	0	94	214	0	0	0	0	
No. **females aborted:**	0	0	0	0	215	0	0	0	0	
Pregnant aborted:	0	0	0	0	214	0	0	0	0	
Corpora lutea/preg. female:	17.4	1.37	12.9	21.70	267	16.4	0.53	15.8	16.80	
I **mplants/preg. female:**	15.6	1.18	11.9	18.2	267	15.4	0.93	14.6	16.4	
% **Pre/peri-implant. loss:**	7.61	4.29	0	24.6	149	5.60	5.12	1	11.3	
Resorptions/preg. female:	0.82	0.34	0	2.0	265	1.03	0.42	0.7	1.5	
% **Resorptions:**	5.35	2.52	0	12.9	120					
Dead fetuses/preg. female:	0.02	0.23	0.0	3.4	225	0	0	0	0	
Live fetuses/preg. female:	14.7	1.15	10.8	17.5	263	14.3	1.21	13.6	15.7	
% **Postimplantation loss:**	6.01	2.47	1.30	14.7	137	6.80	2.55	4.30	9.4	
Sex ratio (% **males):**	50.1	3.32	41.9	61.0	236	54.9	7.85	49.3	60.4	
Live fetal wt. (M+F, **gm):**										
Live female fetal wt. (gm):						5.05	0.07	5.00	5.10	
Live male fetal wt. (gm):						5.30	0	5.30	5.30	
Gravid uterine wt. (gm):										

Crl:CD®(SD)BR Rat, GD 20

Cr1:CD" (SD)BR Rat, GD 21

Total studies:			147					95		
Total mated females:			3,429		**No. of**			2,287		**No. of**
Total pregnant females:			3,247		**Studies**			2,107		**Studies**
	AVG	**S.D.**	**MIN**	**MAX**	**Reported**	AVG	**S.D.**	**MIN**	**MAX**	**Reported**
Age on GD 0 (wks):	12.1	1.94	8	20	138	11.4	2.05	8	17	94
Mated females:	23.3	5.21	10	32	147	24.1	8.19	12	48	95
Pregnant females:	22.1	4.54	10	32	147	22.2	7.72	8	45	95
% **Pregnant** of **mated:**	95.4	6.69	70	100	147	91.5	8.77	57	100	95
No. females all **resorbed:**	0.02	0.15	0	1	90	0.06	0.24	0	1	95
Pregnant all resorbed:	0.05	0.51	0	5	96	1.30	9.80	0	94	93
No. females aborted:	0	0	0	0	95	0	0	0	0	95
Pregnant aborted:	0	0	0	0	95	0	0	0	0	94
Corpora lutea/preg. female:	17.6	1.44	12.9	20.9	147	17.1	1.34	13.6	21.7	95
I **mplants/preg. female:**	15.5	1.11	12.6	18.2	147	15.6	1.30	11.9	18.2	95
% **Pre/peri-implant. loss:**	5.92	4.52	0	17.5	43	8.21	4.01	2	24.6	83
Resorptions/preg. female:	0.79	0.33	0	1.7	147	0.83	0.34	0	1.9	95
Resorptions:	5.06	2.46	1	12.4	43	5.24	2.61	0	12.9	59
Dead fetuses/preg. female:	0.003	0.02	0.0	0.2	109	0.05	0.35	0.0	3.4	95
Live fetuses/preg. female:	14.6	1.07	11.9	17.3	147	14.8	1.29	10.8	17.5	95
Postimplantation loss:	5.59	2.38	1.30	12.4	32	6.02	2.61	1.50	14.7	83
Sex ratio (% **males):**	50.1	3.22	41.9	61.0	147	49.9	3.50	42.2	59.0	89
Live fetal wt. (M+F, **gm):**	3.56	0.19	3.21	4.04	141	4.90	0.61	3.81	5.50	20
Live female fetal wt. (gm):	3.46	0.17	3.10	3.92	99	5.04	0.35	3.69	5.44	91
Live male fetal wt. (gm):	3.65	0.19	3.22	4.15	99	5.32	0.35	3.92	5.70	91
Gravid uterine wt. (gm):	82.3	7.8	66.6	94.7	56	97.5	15.2	71.1	118.0	20

MARTA / MTA

1992-1994

TABLE 3
CESAREAN-SECTION DATA, GESTATION DAY 20
Crl:CD®(SD)BR Rats

Kingston, GD 20

Total studies:			23					90		
Total mated females:			502		No. of			2,147		**No.** of
Total pregnant females:			470		**Studies**			2,018		**Studies**
	AVG	**S.D.**	**MIN**	**MAX**	**Reported**	AVG	**S.D.**	**MIN**	**MAX**	**Reported**
Age on GD 0 (wks):	10.8	2.04	8	15	17	12.6	1.70	10	20	87
Mated females:	21.8	5.15	10	26	*23*	*23.9*	*5.42*	12	30	90
Pregnant females:	20.4	4.71	10	26	*23*	22.4	*4.57*	12	29	90
% **Pregnant** of **mated:**	94.5	7.10	77	100	*23*	*94.8*	7.11	70	100	90
No. females all **resorbed:**	0	0	0	0	17	0.02	0.14	0	1	53
°A° **Pregnant all resorbed:**	0	0	0	0	23	0	0	0	0	53
No. females aborted:	0	0	0	0	23	0	0	0	0	52
% **Pregnant aborted:**	0	0	0	0	23	0	0	0	0	52
Corpora lutea/preg. female:	17.8	1.78	14.6	20.4	23	17.5	1.40	12.9	20.9	90
Implants/preg. female:	15.4	1.15	13.4	17.6	23	15.3	1.15	12.6	18.2	90
% **Pre/peri-implant. loss:**	4.46	4.68	0	14.5	15	9.39	4.50	3	17.5	13
Resorptions/preg. female:	0.79	0.29	0	1.4	23	0.85	0.35	0	1.7	90
Resorptions:	5.72	2.51	3	12.4	15	6.11	2.50	3	11.6	13
Dead fetuses/preg. female:	0.01	0.05	0	0.2	23	0	0	0	0	52
Live **fetuses/preg.** female:	14.6	1.06	12.8	16.6	23	14.5	1.11	11.9	17.3	90
% **Postimplantation loss:**	5.75	2.48	3.00	12.4	15	5.50	2.42	1.30	11.6	16
Sex ratio (% **males):**	49.9	3.95	42.5	61.0	23	50.1	*2.99*	*43.0*	57.0	90
Live fetal wt. (M+F, gm):	3.62	0.23	3.24	4.04	17	3.55	0.18	3.24	4.00	90
Live **female fetal** wt. (gm):	3.53	0.16	3.20	3.92	21	3.42	0.16	3.15	3.76	45
Live **male** fetal wt. (gm):	3.69	0.23	3.22	4.15	21	3.62	0.17	3.32	3.97	45
Gravid uterine wt. (gm):	79.4	8.5	68.6	91.4	9	80.0	7.0	66.6	94.7	30

Raleigh, GD 20

Total studies:			16		
Total mated females:			416		**No.** of
Total pregnant females:			395		**Studies**
	AVG	**S.D.**	**MIN**	**MAX**	**Reported**
Age on GD 0 (wks):	9.8	1.00	9	12	16
Mated females:	26.0	2.56	22	32	16
Pregnant females:	24.7	2.91	20	32	16
% **Pregnant** of **mated:**	94.9	5.72	80	100	16
No. females **all resorbed:**	0	0	0	0	2
Pregnant all resorbed:	0	0	0	0	2
No. females aborted:	0	0	0	0	2
°A) **Pregnant aborted:**	0	0	0	0	2
Corpora lutea/preg. female:	16.8	1.05	15.0	18.40	16
Implants/preg. female:	16.1	0.81	14.4	17.7	16
% **Pre/peri-implant. loss:**	4.38	2.45	1	10.2	15
Resorptions/preg. female:	0.56	0.24	0	1.0	16
°A» **Resorptions:**	3.48	1.55	1	6.3	15
Dead **fetuses/preg. female:**	0.005	0.014	0	0.04	16
Live **fetuses/preg. female:**	15.5	0.72	13.7	16.9	16
% **Postimplantation loss:**	4.43	0	4.43	4.43	1
Sex **ratio** (% **males):**	51.3	3.00	45.5	57.1	16
Live **fetal** wt. (M+F, gm):	3.71	0.07	3.58	3.80	16
Live **female fetal wt. (gm):**	3.59	0.06	3.49	3.69	15
Live male **fetal wt. (gm):**	3.80	0.08	3.58	3.89	15
Gravid uterine wt. (gm):	59.5	3.8	80.1	92.8	14

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TABLE 4

1992-1994 CESAREAN-SECTION DATA, GESTATION DAY 21

Crl:CD®(SD)BR Rats

Kingston, GD 21

						Portage, GD 21				
Total studies:			13					31		
Total mated females:			339		No. of			594		No. of
Total pregnant females:			300		**Studies**			555		Studies
	AVG	**S.D.**	**MIN**	**MAX**	**Reported**	AVG	**S.D.**	**MIN**	**MAX**	**Reported**
Age on GD 0 (wks):	10.8	2.7	8	16	5	13.3	1.78	10	17	31
Mated females:	26.1	7.27	16	48	6	19.2	5.29	12	33	31
Pregnant females:	23.1	3.68	15	29	6	17.9	5.92	8	33	31
Pregnant of **mated:**	91.3	9.24	64	100	6	90.4	9.93	57	100	31
No. **females all resorbed:**	0	0	0	0	6	0.10	0.30	0	1	31
Pregnant all resorbed:	0	0	0	0	5	3.58	17.17	0	94	30
No. females aborted:	0	0	0	0	6	0	0	0	0	31
% **Pregnant aborted:**	0	0	0	0	5	0	0	0	0	31
Corpora lutea/preg. female:	16.9	2.42	13.6	21.70	6	16.4	1.00	14.8	18.30	31
Implants/preg. female:	15.1	1.91	12.1	17.4	6	14.9	1.18	11.9	17.0	31
Pre/peri-implant. loss:	9.30	1.66	7	11.3	5	8.75	4.77	3	24.6	27
Resorptions/preg. female:	0.72	0.34	0	1.3	6	0.89	0.39	0	1.6	31
Resorptions:	3.88	1.69	1	5.5	5	3.30	5.72	0	9.9	3
Dead fetuses/preg. female:	0.26	0.94	0.0	3.4	6	0.01	0.02	0	0.1	31
Live fetuses/preg. female:	14.4	1.69	12.0	16.2	6	13.9	1.10	10.8	15.6	31
Postimplantation loss:	4.49	1.62	3.00	7.0	5	7.14	2.80	3.50	14.7	27
Sex ratio (% **males):**	49.0	5.28	43.0	59.0	5	49.9	4.17	42.2	58.9	30
Live **fetal** wt. (M+F, **gm):**	4.74	0.70	3.81	5.50	6	5.21	0.25	4.98	5.46	4
Live female fetal wt. (gm):	4.49	0.77	3.69	5.36	6	4.99	0.16	4.60	5.31	30
Live **male fetal wt. (gm):**	4.77	0.78	3.92	5.62	6	5.28	0.17	4.90	5.63	30
Gravid **uterine** wt. (gm):	74.4	4.2	71.1	79.4	5	102.9	0	102.9	102.9	

Raleigh, GD 21

Total **studies:**			48		
Total mated females:			1,277		No. of
Total pregnant females:			1,177		**Studies**
	AVG	**S.D.**	**MIN**	**MAX**	**Reported**
Age on GD 0 (wks):	10.3	0.82	9	14	48
Mated females:	26.6	8.88	17	47	48
Pregnant females:	24.5	8.64	12	45	48
Pregnant of **mated:**	91.9	8.09	67	100	48
No. females all **resorbed:**	0.04	0.20	0	1	48
Pregnant all resorbed:	0.20	0.97	0	5	48
No. females aborted:	0	0	0	0	48
% **Pregnant aborted:**	0	0	0	0	48
Corpora lutea/preg. female:	17.6	0.91	15.5	19.60	48
Implants/preg. female:	16.2	0.82	13.9	18.2	48
Pre/peri-implant. loss:	7.69	3.21	2	17.3	48
Resorptions/preg. female:	0.81	0.32	0	1.9	48
Resorptions:	5.43	2.46	2	12.9	48
Dead fetuses/preg. female:	0.02	0.03	0	0.2	48
Live fetuses/preg. female:	15.4	0.90	12.9	17.5	48
% **Postimplantation loss:**	5.52	2.45	1.50	12.9	48
Sex ratio (% **males):**	50.0	2.60	44.0	58.0	48
Live fetal wt. (M+F, **gm):**	5.21	0	5.21	5.21	1
Live **female fetal wt. (gm):**	5.18	0.13	4.94	5.44	48
Live male fetal wt. (gm):	5.46	0.12	5.27	5.70	48
Gravid uterine wt. (gm):	103.9	7.0	92.2	114.7	12

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TABLE 5

CESAREAN-SECTION DATA

Crl:CD°(SD)BR RATS - GESTATION DAY 20

AVERAGES BY COMPANY

Company **number:**	**5**	**9**	**10**	**14**	**15**	**16**	**33**	37
Total **studies:**	4	14	10	6	3	38	3	69
Total mated females:	100	369	250	156	41	1,043	72	1.398
Total pregnant females:	89	350	240	140	38	922	70	1,398
Average age on GD 0 (wks):	8.0	9.5	12.7		11.0	12.3		12.7
Mated females:	25.0	26.4	25.0	26.0	13.7	27.4	24.0	20.3
Pregnant females:	22.2	25.0	24.0	23.3	12.7	24.3	23.3	20.3
% Pregnant of **mated:**	89.0	94.8	96.0	91.7	92.0	88.6	97.2	I00.0
No. females all **resorbed:**	0	0	0	0	0	1.00	0	0.01
% **Pregnant all resorbed:**	0	0	0	0	0	3.44	0	0.07
No. females aborted:	0	0	0	0	0	0	0	0
% **Pregnant aborted:**	0	0	0	0	0	0	0	0
Corpora lutea/preg. female:	15.0	16.6	17.4	18.6	16.8	17.4	13.5	18.1
Implants/preg. female:	13.8	16.0	16.4	15.9	15.3	15.5	12.8	15.3
Pre/peri-implantation loss:	7.99	4.41	5.86	0.00	8.17	12.98		
Resorptions/preg. female:	0.42	0.55	0.89	I.08	0.73	1.02	0.70	0.69
% Resorptions:	3.07	3.41	5.43	7.69	5.07	6.95		
Dead fetuses/preg. female:	0.058	0.006	0	0	0	0	0	0
Live fetuses/preg. female:	13.3	15.4	15.5	14.9	14.6	14.5	12.1	14.6
% **Postimplantation loss:**	3.17		5.43	7.69	5.07	5.65	5.49	
Sex ratio (% **males):**	48.8	51.2	50.7	48.3	53.7	50.0	48.4	50.1
Live fetal wt. (M+F, gm):	3.29	3.70	3.72		3.73	3.56	3.52	3.53
Live female fetal wt. (gm):	3.32	3.59		3.55	3.63		3.42	3.42
Live **male** fetal wt. (gm):	*3.30*	*3.79*		3.75	3.80		3.63	3.62
Gravid **uterine wt. (gm):**	71.5	89.5	92.3		82.3	80.2	69.3	

MARTA / MTA

1992-1994

TABLE 6

CESAREAN-SECTION DATA

Crl:CD®**(SD)BR** RATS - GESTATION DAY 21

AVERAGES BY COMPANY

Company number:	**4**	**5**	**8**	**11**	**18**	**24**	**26**	37
Total **studies:**	2	5	26	33	15	8	2	4
Total mated females:	36	148	471	894	380	191	56	111
Total pregnant females:	33	120	434	826	353	180	50	11 l
Average age on GD 0 (wks):	14.5	8.0	13.6	10.2	10.5	12.7	11.0	10.8
Mated females:	18.0	29.6	18.1	27.1	25.3	23.9	28.0	27.8
Pregnant females:	16.5	24.0	16.7	25.0	23.5	22.5	25.0	27.8
Pregnant of mated:	89.6	86.6	89.1	92.1	92.7	94.3	89.3	100.0
No. **females all resorbed:**	0.50	0	0.12	0.03	0.07	0	0	0
% **Pregnant all resorbed:**	2.15	0	4.29	0.15	0.32	0	0	0
No. females aborted:	0	0	0	0	0	0	0	0
% **Pregnant aborted:**	0	0	0	0	0	0	0	0
Corpora lutea/preg. female:	18.1	14.3	16.2	17.9	17.0	18.5	17.9	17.4
I **mplants/preg. female:**	15.2	13.0	14.8	16.4	15.9	16.5	16.9	14.8
% **Pre/peri-implantation loss:**	15.7	9.30	8.70	8.23	6.24		6.15	
Resorptions/preg. female:	1.30	0.50	0.89	0.69	1.12	0.85	0.70	0.73
% **Resorptions:**		3.88	0.00	4.46	7.66		5.05	
Dead fetuses/preg. female:	0	0.680	0.008	0.023	0	0	0	0
Live fetuses/preg. female:	13.9	12.5	13.9	15.6	14.8	15.6	16.2	14.1
% **Postimplantation loss:**	8.55	4.49	7.04	4.60	7.66		5.05	
Sex ratio (% **males):**	46.6	50.3	50.4	50.1	50.0	46.7	53.5	46.5
Live fetal wt. (M+F, **gm):**	4.89	3.91				5.27	5.29	5.21
Live female fetal wt. (gm):	4.80	3.77	4.98	5.20	5.15	5.22	5.11	5.08
Live male fetal wt. (gm):	4.99	4.04	5.27	5.48	5.41	5.49	5.43	5.36
Gravid uterine wt. (gm):	102.9	74.4			103.6		116.3	

MARTA / MTA

1992-1994

TABLE 7

NATURAL **DELIVERY** DATA IN Crl:CD®**(SD)BR** RATS

Average and S.D. are calculated on a per study basis

	All Studies				Rats from Kingston			
Total studies:	149				30			
Total mated females:	3,148				687			
Total pregnant females:	2,872				561			
	AVG	**S.D.**	**MIN**	**MAX**	AVG	**S.D.**	**MIN**	**MAX**
Average age on GD 0 (wks):	13.0	3.16	10	28	14.2	2.98	10	21
Length of gestation (days):	22.3	0.44	21.2	23.3	22.4	0.57	21.2	23.3
Mated females/study:	21.6	6.08	5	35	22.9	7.98	5	30
Pregnant females/study:	19.5	5.43	5	35	18.7	6.27	5	29
% Pregnant of mated:	93.0	9.88	60	100	86.7	11.47	60	100
No. **females all resorbed:**	0.09	0.44	0	4	0.00	0.00	0	0
% **Pregnant all resorbed:**	0.42	1.97	0	18	0.00	0.00	0	0
Females with live pups:	19.3	5.58	0.0	35	19.1	6.42	5.0	29
% Females with live pups:	97.3	10.26	0.0	100	93.4	8.21	78.6	100
Implants/pregnant female:	16.05	1.38	11.50	19.00	16.22	1.44	13.80	18.60
Postimplantation loss:	8.80	*3.33*	0.00	20.40	9.09	4.02	0.90	15.03
No. live pups/litter:	14.46	1.32	9.60	17.60	14.07	1.16	12.20	16.60
No. stillborn/litter:	0.29	0.66	0.00	7.00	0.26	0.22	0.00	0.80
% Stillborn/litter:	1.22	1.96	0.00	10.20	1.45	1.34	0.00	4.00
Day of culling (0=birth):	4.39	1.45	0.00	7.00	4.48	1.12	4.00	7.00
Pups/litter after culling:	7.93	0.48	6.50	11.60	7.73	0.35	6.50	8.00
% Dead pups PND 1 to prior culling:	2.76	2.76	0.00	13.10	1.97	2.30	0.00	7.90
% Dead pups postculling to PND 21:	0.71	1.28	0.00	8.60	0.79	1.11	0.00	3.75
Sex ratio at **birth** (% **males):**	50.00	3.39	39.00	59.50	49.81	3.53	44.00	59.00
Live combined birth weight:	6.47	0.43	5.70	7.71	6.68	0.28	6.10	7.10
Live female birth weight:	6.31	0.36	5.60	7.54	6.51	0.25	6.07	7.10
Live male birth weight:	6.66	0.37	5.99	7.86	6.86	0.24	6.36	7.25
Live combined PND 4 weight:	9.77	1.03	8.10	12.30	10.63	0.94	8.40	12.30
Live female PND 4 weight:	9.74	1.12	7.48	12.00	10.49	0.90	8.85	12.00
Live male PND 4 weight:	10.21	1.09	8.01	12.70	10.88	0.86	9.41	12.70
Live combined PND 7 **weight:**	15.84	3.50	12.10	39.80	16.84	1.86	13.60	19.80
Live female PND 7 **weight:**	16.02	2.19	10.90	19.30	16.88	1.47	13.82	19.30
Live male PND 7 **weight:**	16.74	2.29	11.59	20.50	17.19	1.90	12.00	20.30
Live combined PND 14 weight:	33.78	6.22	22.90	77.60	35.44	2.14	31.83	40.00
Live female PND 14 weight:	34.08	3.24	27.62	39.10	34.91	2.11	30.39	39.10
Live male PND 14 weight:	35.37	3.27	29.08	41.00	36.05	2.18	32.00	41.00
Live combined PND 21 weight:	53.67	11.32	33.70	125.8	56.47	4.24	49.50	62.70
Live female PND 21 **weight:**	54.51	5.64	34.65	63.40	56.55	3.05	50.38	61.10
Live male PND 21 **weight:**	56.82	5.94	36.05	67.30	58.69	3.31	52.54	*64.30*

MARTA / MTA

1992-1994

TABLE 7 (Continued)
NATURAL DELIVERY DATA
IN Crl:CD®(SD)BR RATS

Average and S.D. are calculated on a per study basis

Rats from Portage

Rats from Raleigh

Total **studies:**	149				50			
Total mated females:	3,148				1,064			
Total pregnant females:	2,872				990			
	AVG	**S.D.**	**MIN**	**MAX**	**AVG**	**S.D.**	**MIN**	**MAX**
Average age on GD 0 (wks):	13.6	2.99	10	28	11.7	2.54	10	19
Length of gestation (days):	22.2	0.39	21.3	23.2	22.2	0.34	21.3	22.7
Mated females/study:	21.1	6.43	10	35	21.3	4.28	13	35
Pregnant females/study:	19.5	5.89	10	31	19.8	4.38	11	35
% **Pregnant** of **mated:**	96.2	8.25	67	100	93.1	9.04	63	100
No. females all resorbed:	0.05	0.21	0	1	0.18	0.63	0	4
%Pregnant all resorbed:	0.18	0.83	0	4	0.87	2.94	0	18
Females with live pups:	19.2	5.80	9.0	31	19.2	5.15	0.0	35
%Females with live pups:	98.7	2.92	89.0	100	97.0	14.31	0.0	100
Implants/pregnant female:	15.57	1.21	11.50	17.80	16.59	1.35	11.80	19.00
% **Postimplantation loss:**	8.86	2.79	5.30	16.80	8.70	3.40	0.00	20.40
No. live pups/litter:	14.07	1.23	9.60	16.60	15.26	1.14	12.30	17.60
No. **stillborn/litter:**	0.27	0.42	0.00	3.00	0.35	1.02	0.00	7.00
%Stillborn/litter:	0.26	0.58	0.00	1.70	1.76	2.83	0.00	10.20
Day of culling (0=birth):	4.54	1.40	1.00	7.00	4.09	1.78	0.00	7.00
Pups/litter after culling:	8.04	0.66	7.00	11.60	7.99	0.09	7.50	8.00
%Dead pups PND 1 to prior culling:	2.66	1.98	0.00	9.00	3.15	3.58	0.00	13.10
%Dead pups postculling to PND 21:	0.43	0.78	0.00	3.30	0.99	1.74	0.00	8.60
Sex ratio at birth (%a **males):**	49.91	3.38	41.90	59.50	50.13	3.48	39.00	56.90
Live combined birth weight:	6.22	0.27	5.70	6.79	7.09	0.45	6.30	7.71
Live female birth weight:	6.01	0.20	5.60	6.60	6.39	0.38	5.61	7.54
Live male birth weight:	6.38	0.23	6.00	6.99	6.73	0.39	5.99	7.86
Live combined PND 4 weight:	9.21	0.58	8.10	10.70	10.40	0.92	9.06	11.89
Live female PND 4 weight:	9.24	0.69	8.30	10.80	9.27	1.30	7.48	11.78
Live male PND 4 weight:	9.80	0.75	8.90	11.50	9.75	1.31	8.01	12.06
Live combined PND 7 **weight:**	14.60	1.60	12.10	17.70	19.16	7.50	12.70	39.80
Live female PND 7 **weight:**	14.91	1.60	13.10	18.10	16.27	2.59	10.90	19.30
Live male PND 7 **weight:**	15.80	1.70	14.00	18.90	17.12	2.68	11.59	20.50
Live combined PND 14 weight:	31.64	2.97	22.90	37.27	39.88	13.56	30.20	77.60
Live female PND 14 weight:	31.62	2.84	27.90	37.10	35.28	3.20	27.62	39.03
Live male PND 14 weight:	33.09	3.04	29.50	38.70	36.56	3.22	29.08	40.40
Live combined PND 21 weight:	49.43	6.32	*33.70*	64.38	62.89	22.85	42.60	125.8
Live female PND 21 weight:	50.99	4.23	44.20	62.32	*56.79*	6.34	34.65	63.40
Live male PND 21 weight:	53.42	4.66	47.40	66.45	59.09	6.78	36.05	67.30

TABLE 8
NATURAL DELIVERY DATA
IN Crl:CD®(SD)BR RATS
AVERAGES BY COMPANY

Company number:	4	8	9	11	14	15	16
Total studies:	3	14	8	31	6	1	19
Mated females:	58	280	207	617	134	10	486
Pregnant females:	52	267	179	580	114	8	405
Average age on GD 0 (wks):	13.0	14.1	16.4	10.7		11.0	12.0
Length of gestation (days):	22.2	22.0	22.3	22.3	23.1	21.8	22.1
Mated females/study:	19.3	20.0	25.9	19.9	22.3	10.0	27.0
Pregnant females/study:	17.3	19.1	22.4	18.7	19.0	8.0	22.5
Pregnant of mated:	88.4	92.6	86.9	93.7	85.2	80.0	86.2
No. females all resorbed:	0.3	0.1	0.4	0.1		0.0	
% Pregnant all resorbed:	1.4	0.3	1.8	0.3	0.0	0.0	
Females with live pups:	17.0	18.6	22.0	17.9		8.0	22.1
% Females with live pups:	98.6	97.5	98.2	96.1		100.0	
Implants/pregnant female:	15.1	15.4	14.9	16.9	16.2	14.9	15.4
% Postimplantation loss:	11.6	8.3	9.6	9.0	10.0	0.9	
No. live pups/litter:	13.3	14.1	14.1	15.6	14.4	14.4	13.9
No. stillborn/litter:	0.2	0.2	0.4	0.4	0.3	0.0	0.4
Stillborn/litter:	0.7	1.4	2.8		1.6	0.0	
Day of culling (0=birth):	3.0	4.0	4.0	2.8	4.0		4.0
Pups/litter after culling:	8.0	8.0	8.0	8.0	8.0		
% Dead pups PND 1 to prior culling:	1.5	2.7	4.3	1.1	1.5		
Dead pups postculling to PND 21:	0.0	1.0	1.4	1.0	1.2		
Sex ratio at birth (% males):	47.9	50.5	50.7	49.4	50.8	59.0	50.3
Live combined birth weight:	6.4		7.2				6.1
Live female birth weight:	6.2	6.0	7.0	6.3	6.3		6.0
Live male birth weight:	6.6	6.4	7.4	6.7	6.6		6.4
Live combined PND 4 weight:			10.6			10.8	9.7
Live female PND 4 weight:		8.9	10.3		9.7	10.5	9.8
Live male PND 4 weight:		9.5	10.8		10.1	11.0	10.5
Live combined PND 7 weight:	17.0		139.1	39.8			160.2
Live female PND 7 weight:	16.4	14.0	16.8	17.9	15.6		16.7
Live male PND 7 weight:	17.6	14.9	17.8	**18.8**	16.3		17.6
Live combined PND 14 weight:	37.3		36.4	77.6			32.8
Live female PND 14 weight:	36.2	30.1	35.7	37.1	33.2		34.5
Live male PND 14 weight:	38.4	31.5	37.0	38.4	34.3		36.1
Live combined PND 21 weight:	59.5		57.6	125.8			60.7
Live female PND 21 weight:	57.5	49.0	53.8	60.7	55.0		52.1
Live male PND 21 weight:	61.3	51.6	55.7	63.3	57.0		54.3

TABLE 8 (Continued)
NATURAL DELIVERY DATA
IN Crl:CD®(SD)BR RATS
AVERAGES BY COMPANY

Company number:	18	19	24	33	37
Total studies:	10	5	13	2	37
Mated females:	208	81	361		706
Pregnant females:	199	71	267	24	706
Average age on GD 0 (wks):	11.3	12.6	16.5		13.6
Length of gestation (days):	21.5	21.4	22.5	21.6	22.5
Mated females/study:	20.8	16.2	27.8		19.1
Pregnant females/study:	19.9	14.2	20.5	24.0	19.1
% Pregnant of mated:	95.3	90.6	80.2		100.0
No. females all resorbed:	0.4	0.0	0.0		0.0
Pregnant all resorbed:	2.0	0.0	0.0		0.0
Females with live pups:	19.5	16.5	20.5	24.0	18.9
% Females with live pups:	98.2	100.0	82.8		99.2
Implants/pregnant female:	16.8	16.6			15.8
Postimplantation loss:	6.6	9.6			
No. live pups/litter:	15.5	14.7	13.6	12.0	14.3
No. stillborn/litter:	0.1	0.2	0.3	0.0	0.2
% Stillborn/litter:	0.7	1.1	2.0	0.0	0.0
Day of culling (0=birth):	7.0	4.0	4.0	4.0	5.4
Pups/litter after culling:	8.0	7.9	7.6	8.0	7.9
% Dead pups PND 1 to prior culling:	7.0	0.7		2.5	2.9
Dead pups postculling to PND 21:	0.6	0.4	0.0	0.0	0.3
Sex ratio at birth (% males):	*52.5*	*49.3*	*49.2*		49.7
Live combined birth weight:		6.8	6.7		6.3
Live female birth weight:	6.0	6.7	6.6	5.9	
Live male birth weight:	6.3	7.0	6.9	6.1	
Live combined PND 4 weight:		10.1	11.2		9.0
Live female PND 4 weight:	8.1	9.9	11.0	9.6	
Live male PND 4 weight:	8.6	10.4	11.4	9.8	
Live combined PND 7 weight:		31.8	216.4		520.6
Live female PND 7 weight:	12.0	15.5	17.7	15.2	
Live male PND 7 weight:	12.6	16.3	17.8	15.7	
Live combined PND 14 weight:		33.8	36.6		31.3
Live female PND 14 weight:	30.1	33.3	36.0	31.8	
Live male PND 14 weight:	31.3	34.2	37.2	32.4	
Live combined PND 21 weight:		55.5	58.8		48.5
Live female PND 21 weight:	50.2	54.6	57.7	50.2	
Live male PND 21 weight:	52.1	56.3	59.9	51.3	

TABLE 9
EXTERNAL ALTERATIONS IN CrH:CD®(SD)BR RATS
GESTATION DAYS 20 AND 21

Total studies: 229
Total litters: 4.935
Total fetuses: 64.789

	FETAL INCIDENCE				LITTER INCIDENCE			
	No.	Avg(%)	S.D.	Max	No.	Avg(%)	S.D.	Max
Ablepharia :	3	0.009	0.13	1.74	1	0.048	0.66	9.10
Acaudia :		0.001	0.01	0.10		0.014	0.19	2.60
Acephalostomia :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Acephaly :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Acrania :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Adactyly :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Aglossia :		0.002	0.02	0.30		0.025	0.35	4.80
Agnathia :	5	0.011	0.07	0.70	5	0.133	0.83	7.10
Amelia (=Ectromelia) :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Anasarca :	9	0.014	0.07	0.65	8	0.189	0.93	7.10
Anencephaly :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Ankylosis :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Anophthalmia :	8	0.016	0.08	0.58	8	0.241	1.21	9.10
Anotia :	1	0.001	0.02	0.27		0.022	0.31	4.20
Apodia :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Arrhinia :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Arthrogryposis :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Astomia :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Atresia ani :	5	0.008	0.06	0.61	5	0.119	0.89	9.50
Bowed limb :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Brachydactyly :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Cephalocele	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Claw Agenesis	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Claw Displaced	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Claw Hypoplastic	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Cleft face :	6	0.017	0.21	2.91	2	0.071	0.73	9.10
Cleft lip :	3	0.005	0.04	0.41	3	0.075	0.60	5.60
Cleft palate :	18	0.036	0.22	2.91	14	0.323	1.22	9.10
Club foot :	1	0.001	0.02	0.24		0.023	0.32	4.40
Conjoined twins	1	0.001	0.02	0.23		0.022	0.31	4.20
Craniorachischisis :	3	0.005	0.04	0.44	3	0.075	0.60	5.90
Cranioschisis :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Cyclopia :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Digit enlarged :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Digit misdirected :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Digit misshapen	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Domed head		0.002	0.03	0.36		0.026	0.36	5.00
Ectopia cordis :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Ectrodactyly		0.002	0.02	0.31		0.024	0.33	4.50
Encephalocele	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Encephalomeningocele :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Ethmocephaly	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Exencephaly :	13	0.029	0.23	2.91	7	0.206	1.11	9.10
Exophthalmos :	2	0.003	0.03	0.29	2	0.044	0.43	4.30
Gastroschisis :	4	0.007	0.05	0.41	4	0.103	0.72	6.70
Genital tubercle Agenesis :	1	0.002	0.03	0.44	1	0.031	0.43	5.90
Genital tubercle Fused (to tail) :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Genital tubercle Hypoplastic :	0	0.000	0.00	0.00	0	0.000	0.00	0.00

	FETAL INCIDENCE				LITTER INCIDENCE			
	No.	Avg(%)	S.D.	Max	No.	Avg(%)	S.D.	Max
Hematoma :	11	0.022	0.12	1.24	11	0.301	1.49	13.30
Hemimelia :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
High-arched palate :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Holorachischisis :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Hydramnios :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Hydrocephaly :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Kyphosis :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Limb Hyperextension :		0.001	0.02	0.25	1	0.019	0.26	3.60
Limb Hyperflexion :	5	0.014	0.16	2.10	4	0.101	0.86	10.00
Limb Rotation :		0.002	0.03	0.36	1	0.024	0.33	4.50
Local edema	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Lordosis :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Macroglossia	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Macrognathia :	2	0.003	0.03	0.32	2	0.047	0.45	4.50
Macrophthalmia :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Macrotia :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Meningocele	2	0.004	0.03	0.36	2	0.048	0.46	4.50
Microcephaly	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Microglossia		0.001	0.02	0.26	1	0.023	0.31	4.30
Micrognathia	10	0.018	0.08	0.56	10	0.256	1.11	7.10
Micromelia :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Microphthalmia :	5	0.008	0.05	0.41	5	0.126	0.77	5.60
Microstomia	1	0.003	0.05	0.65		0.024	0.33	4.50
Microtia :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Naris/Nasal Agenesis :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Naris/Nasal Atresia :	2	0.004	0.04	0.41	2	0.051	0.50	5.60
Naris/Nasal Displaced :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Naris/Nasal Hypoplastic :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Naris/Nasal Misshapen :	1	0.002	0.03	0.40	0	0.000	0.00	0.00
Naris/Nasal single naris :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Oligodactyly (= ectrodactyly) :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Oligohydramnios :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Omphalocele :	6	0.010	0.06	0.60	6	0.140	0.88	8.00
Open eye/eyelid(s) :	4	0.006	0.04	0.36	4	0.097	0.66	5.00
Otocephaly:	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Palate rugae Agenesis :		0.003	0.05	0.65	1	0.023	0.31	4.30
Palate rugae Hypoplastic :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Palate rugae Misshapen :	1	0.002	0.03	0.40	0	0.000	0.00	0.00
Phocomelia :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Pinnae Agenesis :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Pinnae Displaced :	4	0.008	0.06	0.56	4	0.111	0.77	7.10
Pinnae Misshapen :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Polydactyly :	3	0.006	0.05	0.50	3	0.071	0.59	5.90
Polysyndactyly :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Protruding tongue :	8	0.014	0.10	1.07	5	0.122	0.74	5.00
Rhinocephaly :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Scoliosis :	1	0.001	0.02	0.28		0.022	0.31	4.20
Spina bifida :	1	0.002	0.02	0.32		0.025	0.35	4.80
Sympodia :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Syndactyly :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Synotia :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Tail Agenesis		0.002	0.02	0.30	1	0.023	0.31	4.30
Tail Blunt-tipped :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Tail Coarcted	0	0.000	0.00	0.00	0	0.000	0.00	0.00

	FETAL INCIDENCE				LITTER INCIDENCE			
	No.	**Avg(%)**	**S.D.**	Max	No.	**Avg(%)**	**S.D.**	**Max**
Tail Corkscrew :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Tail Displaced :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Tail Double-tipped :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Tail Filamentous :	11	0.017	0.07	0.36	11	0.250	1.01	4.80
Tail Fleshy tab :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Tail Hooked :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Tail Hypoplastic :	1	0.002	0.02	0.30	1	0.025	0.35	4.80
Tail Kinked :	2	0.003	0.03	0.28	2	0.043	0.42	4.20
Thoracogastroschisis :	1	0.001	0.02	0.26	1	0.021	0.29	4.00
Thoracoschisis :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Umbilical hernia :	3	0.004	0.04	0.33	3	0.067	0.54	5.30

TABLE 10
VISCERAL ALTERATIONS IN Cr1:CD®(SD)BR RATS
GESTATION DAYS 20 AND 21

Total studies: 229
Total litters: 4.935
Total fetuses: 24.340

	FETAL INCIDENCE				LITTER INCIDENCE			
	No.	Avg(%)	S.D.	Max	No.	Avg(%)	S.D.	Max
A-V ostium, Enlarged :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
A-V septal defect :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Adrenal gland, Agenesis :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Adrenal gland, Displaced :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Adrenal gland, Enlarged :	1	0.006	0.07	0.80	1	0.037	0.43	5.00
Adrenal gland, Extracapsular tissue :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Adrenal gland, Fused :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Adrenal gland, Hemorrhagic :	1	0.008	0.10	1.11	1	0.075	0.86	10.00
Adrenal gland, Hypoplastic :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Adrenal gland, Misshapen :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Aneurysm :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Anophthalmia-bilateral :	1	0.005	0.05	0.63	1	0.037	0.43	5.00
Anophthalmia-unilateral :	2	0.005	0.06	0.70	2	0.063	0.51	4.20
Aortic arch, Enlarged diameter :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Aortic arch, Interrupted :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Aortic arch, Retroesophageal :	1	0.015	0.17	2.00	1	0.075	0.86	10.00
Aortic valve, Agenesis :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Aortic valve, Enlarged :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Aortic valve, Hypoplastic :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Aortic valve, Misshapen :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Aortic valve. Supernumerary :	1	0.004	0.05	0.60	1	0.032	0.37	4.30
Aorticopulmonary septal defect :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Ascending aorta, Enlarged diam. :	1	0.004	0.04	0.50	1	0.034	0.40	4.60
Ascending aorta, Hypoplastic :	1	0.002	0.02	0.25	1	0.028	0.33	3.80
Atrial septa(defect :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Atrioventricular canal, Persistent :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Atrioventricular valve, Agenesis :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Atrioventricular valve, Enlarged :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Atrioventricular valve, Hypoplastic :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Atrioventricular valve, Misshapen :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Atrioventricular valve, Supernum.:	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Azygos vein, Right-sided :	5	0.028	0.15	0.93	5	0.171	0.88	5.60
Azygos vein, Supernumerary :	16	0.092	0.38	2.50	14	0.510	2.05	14.30
Bile duct, Elongated :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Bile duct, Shortened :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Cardiomegaly :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Carotid, Displaced :	2	0.017	0.17	2.00	2	0.106	0.93	10.00
Cataract :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Cerebellum/Cerebrum, Hypoplastic :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Cerebellum/Cerebrum, Misshapen :	2	0.046	0.48	5.56	2	0.081	0.66	5.60
Cerebral Ventricle, Enlargement :	756	2.573	11.49	87.84	185	5.448	17.19	100.00
Cor biloculare :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Cor triloculare :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Cryptorchidism :	15	0.049	0.41	4.20	13	0.375	2.63	20.80
Dextrocardia :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Diaphragmatic hernia :	6	0.026	0.14	1.04	6	0.234	1.26	9.10

	FETAL INCIDENCE				LITTER INCIDENCE			
	No.	Avg(%)	S.D.	Max	No.	Avg(%)	S.D.	Max
Ductus arteriosus, Hypoplastic :	4	0.018	0.15	1.25	3	0.107	0.94	10.00
Epididymis, Any Alteration :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Esophagus, Atresia :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Esophagus, Shortened :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Gallbladder, Agenesis :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Gallbladder, Enlarged :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Gallbladder, Hypoplastic :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Gallbladder, Misshapen :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Gallbladder, Supernumerary	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Gastromegaly :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Hepatomegaly :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Hermaphroditism :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Hydrocephaly:	7	0.027	0.16	1.43	6	0.198	0.92	5.00
Hydronephrosis :	19	0.063	0.39	3.90	15	0.437	1.79	12.50
Hydroureter :	90	0.308	1.95	21.62	38	1.131	4.59	41.40
Innominate, Agenesis :	10	0.048	0.20	1.40	10	0.364	1.41	9.10
Innominate, Hypoplastic :	2	0.012	0.09	0.83	2	0.063	0.52	4.30
Intestines, Any Alteration :	1	0.001	0.02	0.20		0.019	0.22	2.60
Kidney, Agenesis :		0.002	0.02	0.23		0.032	0.37	4.30
Kidney, Displaced :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Kidney, Elongated :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Kidney, Enlarged :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Kidney, Fused :		0.004	0.04	0.48		0.036	0.41	4.80
Kidney, Hypoplastic :	53	0.200	1.32	12.38	33	1.026	6.45	52.00
Kidney, Misshapen :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Kidney, Supernumerary :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Lens, Agenesis :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Lens, Hypoplastic	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Lens, Misshapen :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Levocardia :		0.005	0.06	0.65	1	0.032	0.37	4.30
Liver, Agenesis of lobe(s) :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Liver, Displaced :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Liver, Enlarged lobe(s) :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Liver, Fused lobes :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Liver, Hemorrhagic :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Liver, Hypoplastic	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Liver infarct	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Liver, Misshapen :		0.006	0.07	0.83		0.032	0.37	4.30
Liver, Mottled :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Liver, Pale	2	0.008	0.10	1.10	1	0.034	0.39	4.50
Liver, Supernumerary lobe :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Liver, Unilobular	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Lung, Agenesis of caudate :	2	0.009	0.07	0.63	2	0.071	0.58	5.00
Lung, Agenesis of lobe(s) :		0.002	0.02	0.26	1	0.031	0.36	4.20
Lung, Displaced :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Lung, Enlarged lobe(s) :	1	0.002	0.02	0.26	1	0.031	0.36	4.20
Lung, Fused lobes		0.005	0.05	0.63	1	0.037	0.43	5.00
Lung, Hemorrhagic :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Lung, Hypoplastic :	28	0.127	0.64	4.64	20	0.696	3.27	22.70
Lung, Hypoplastic caudate :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Lung infarct :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Lung, Misshapen :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Lung, Mottled	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Lung, Pale :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Lung, Supernumerary lobe(s) :	0	0.000	0.00	0.00	0	0.000	0.00	0.00

	FETAL INCIDENCE				LITTER INCIDENCE			
	No.	Avg(%)	S.D.	Max	No.	Avg(%)	S.D.	Max
Lung, Unilobular :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Macrophthalmia-unilateral:	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Macrophthalmia-bilateral	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Microblepharia	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Microcardia	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Microphthalmia-unilateral	4	0.017	0.10	0.60	4	0.135	0.78	5.30
Microphthalmia-bilateral:	5	0.028	0.15	1.14	5	0.204	1.06	7.10
Nasal cavity, Enlarged	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Nasal cavity, Hypoplastic	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Nasal septa!, Agenesis	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Ovary, Any Alteration	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Oviduct, Any Alteration :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Pancreas, Any Alteration :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Pericardial edema	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Pseudohermaphroditism	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Pulmonary, Enlarged diameter	1	0.006	0.07	0.83	1	0.038	0.44	5.00
Pulmonary, Retroesophageal	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Pulmonary, Stenosis :	3	0.014	0.12	1.20	2	0.069	0.57	5.00
Pulmonary valve, Agenesis :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Pulmonary valve, Enlarged	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Pulmonary valve, Hypoplastic	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Pulmonary valve, Misshapen	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Pulmonary valve, Supernumerary	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Rectum, Any Alteration	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Renal pelvis, Dilated	278	1.174	2.67	19.66	172	6.463	11.88	58.80
Renal pelvis, Hypoplastic	101	0.457	1.91	14.00	55	2.056	7.98	57.10
Retina. Coloboma	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Retina, Rossette formation :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Retinal fold	5	0.031	0.19	1.56	4	0.156	0.90	6.30
Seminal vesicle, Agenesis :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Situs Inversus	10	0.049	0.22	2.00	10	0.403	1.50	10.00
Spleen, Agenesis	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Spleen, Bipartite :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Spleen, Hypoplastic	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Spleen, Misshapen :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Spleen, Supernumerary	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Splenomegaly	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Stomach, Any Alteration :	1	0.004	0.05	0.58		0.031	0.36	4.20
Subclavian, Displaced .	1	0.006	0.07	0.80		0.034	0.39	4.50
Subclavian, Retroesophageal	4	0.018	0.12	1.20	3	0.132	0.94	9.10
Testis, Agenesis	1	0.006	0.07	0.83		0.032	0.37	4.30
Testis, Displaced :	5	0.032	0.24	1.90	5	0.225	1.62	13.00
Testis, Hypoplastic :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Testis, Supernumerary	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Tetralogy of Fallot	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Thymus, Agenesis	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Thymus, Bipartite :	11	0.062	0.38	3.10	8	0.317	1.99	16.70
Thymus, Displaced :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Thymus, Hemorrhagic :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Thymus, Hypoplastic	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Thymus, Misshapen :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Trachea, Displaced :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Trachea, Stenosis :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Tracheoesophageal fistula .	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Truncus communis :	16	0.062	0.33	2.41	14	0.457	2.38	19.00

	FETAL INCIDENCE				LITTER INCIDENCE			
	No.	**Avg(%)**	**S.D.**	**Max**	**No.**	**Avg(%)**	**S.D.**	**Max**
Ureter, Agenesis :	1	0.002	0.02	0.23	1	0.032	0.37	4.30
Ureter, Convoluted :	131	0.758	4.52	45.08	61	2.396	11.41	90.00
Ureter, Distended sl to mod :	601	2.472	4.82	31.34	343	12.39	17.97	90.00
Ureter, Fused :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Ureter, Retrocaval :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Ureter, Shortened :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Ureter, Stenosis :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Urinary bladder, Agenesis	2	0.007	0.06	0.53	2	0.075	0.62	5.90
Urinary bladder, Distended	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Urinary bladder, Hypoplastic :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Uterine horn, Any Alteration	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Vas deferens, Any Alteration :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Vena cava, Any Alteration :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Ventricle, Enlarged :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Ventricle, Hypoplastic	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Ventricular septal defect, Membran.	44	0.260	1.44	10.30	30	1.018	5.61	40.90
Ventricular septal defect, Muscular	4	0.018	0.13	1.34	4	0.134	0.98	10.00

TABLE 11
SKELETAL ALTERATIONS IN CrH:CD®(SD)BR RATS
GESTATION DAY 20

Total **studies:** 109
Total litters: 2.320
Total **fetuses:** 15.440

	FETAL INCIDENCE				LITTER INCIDENCE			
	No.	**Avg(%)**	**S.D.**	**Max**	**No.**	**Avg(%)**	**S.D.**	**Max**
Abasophalangy :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Acrania :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Alisphenoid Any Alteration :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Amesophalangy :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Aphalangy :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Atelephalangy :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Atlas Bipartite :	2	0.020	0.12	0.80	2	0.124	0.76	5.00
Atlas Hypoplastic :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Basioccipital Any Alteration :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Basisphenoid Misshapen :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Cervical Centra/Arch Agenesis :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Cervical Centra/Arch Bipartite :	16	0.092	0.34	1.87	13	0.773	2.80	15.00
Cervical Centra/Arch Dumbbell :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Cervical Centra/Arch Fused :	3	0.019	0.10	0.60	3	0.172	0.85	4.50
Cervical Centra/Arch Hemicentra :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Cervical Centra/Arch Hypoplastic :	40	0.254	1.85	15.89	19	1.251	8.36	70.00
Cervical Centra/Arch Misaligned :	1	0.006	0.05	0.45	1	0.060	0.52	4.50
Cervical Centra/Arch Misshapen :	2	0.013	0.08	0.50	2	0.123	0.75	4.70
Cervical Centra/Arch Supernum. :	29	0.151	1.16	10.00	17	0.928	6.63	56.00
Clavicle/Scapula Agenesis :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Clavicle/Scapula Elongated :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Clavicle/Scapula Hypoplastic :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Clavicle/Scapula Misshapen :	2	0.013	0.08	0.59	2	0.116	0.71	4.50
Craniostenosis :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Exoccipital Any Alteration :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Femur Bowed :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Femur Hypoplastic :	1	0.008	0.07	0.59	I	0.060	0.52	4.50
Femur Misshapen :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Fibula Bowed :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Fibula Hypoplastic :	I	0.008	0.07	0.59	1	0.060	0.52	4.50
Fibula Misshapen :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Fontanel Enlarged :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Frontal Bone island :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Frontal Fused :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Frontal Hypoplastic :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Frontal Misshapen :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Humerus Hypoplastic :	1	0.008	0.07	0.59	1	0.060	0.52	4.50
Humerus Misshapen :	1	0.006	0.05	0.42	1	0.056	0.48	4.20
Hyoid Bone Agenesis :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Hyoid Bone Hypoplasic :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Hyoid Bone Misshapen :	12	0.155	1.35	11.65	6	0.667	5.77	50.00
llium/lschium/Pubis Agenesis :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
llium/lschium/Pubis Elongated :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
llium/lschium/Pubis Hypoplastic :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
llium/lschium/Pubis Misaligned :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
llium/lschium/Pubis Misshapen :	1	0.008	0.07	0.59	1	0.060	0.52	4.50
llium/lschium/Pubis Thickened :	0	0.000	0.00	0.00	0	0.000	0.00	0.00

	FETAL INCIDENCE				LITTER INCIDENCE			
	No.	Avg(%)	S.D.	Max	No.	Avg(%)	S.D.	Max
Interparietal Bipartite :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Interparietal Bone island :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Interparietal Fused :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Interparietal Hypoplastic :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Lumbar Centra/Arch Agenesis :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Lumbar Centra/Arch Bipartite :	35	0.139	0.58	4.57	21	1.155	4.77	36.00
Lumbar Centra/Arch Dumbbell :	25	0.084	0.70	6.09	13	0.691	5.55	48.00
Lumbar Centra/Arch Fused :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Lumbar Centra/Arch Hemicentra :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Lumbar Centra/Arch Hypoplastic :	1	0.008	0.07	0.63	1	0.064	0.55	4.80
Lumbar Centra/Arch Misaligned :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Lumbar Centra/Arch Misshapen :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Lumbar Centra/Arch Supernum.:	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Malar (=Zygomatic) Any Alter. :	1	0.008	0.07	0.63	1	0.064	0.55	4.80
Mandible Agenesis :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Mandible Hypoplastic :	2	0.022	0.14	1.10	2	0.155	0.96	7.10
Mandible Misshapen :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Maxilla Agenesis :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Maxilla Hypoplastic :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Maxilla Misshapen :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Metacarpus/Metatarsus Agen.:	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Metacarpus/Metatarsus Hypopl. :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Multiple skull bone alterations :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Nasal Bone island :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Nasal Fused :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Nasal Hypoplastic :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Nasal Misshapen :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Palatine Any Alteration :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Parietal Agenesis :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Parietal Bone island :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Parietal Fused :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Parietal Hypoplastic :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Parietal Misshapen :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Phalanx Agenesis :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Phalanx Fused :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Phalanx Misaligned :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Phalanx Supernumerary :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Premaxilla Any Alteration :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Presphenoid Any Alteration :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Radius Hypoplastic :	1	0.008	0.07	0.59	1	0.060	0.52	4.50
Radius Misshapen :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Rib Agenesis :	2	0.01 I	0.07	0.53	2	0.109	0.67	4.20
Rib Branched :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Rib Cervical-bilateral :	25	0.197	0.42	2.14	22	1.289	2.68	13.60
Rib Cervical-unilateral :	13	0.087	0.40	3.14	11	0.620	2.46	16.70
Rib Clubbed :	17	0.126	0.59	4.69	12	0.669	2.57	16.70
Rib Discontinuous :	2	0.010	0.06	0.50	2	0.107	0.65	4.00
Rib Fused :	8	0.055	0.17	0.80	8	0.471	1.38	5.60
Rib Hypoplastic :	60	0.309	1.56	11.26	32	1.772	6.99	45.80
Rib Intercostal :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Rib Knobby :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Rib Misaligned :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Rib Misshapen :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Rib Thickened :	6	0.033	0.16	1.14	6	0.349	1.72	13.00

	FETAL INCIDENCE				LITTER INCIDENCE			
	No.	Avg(%)	S.D.	Max	No.	Avg(%)	S.D.	Max
Rib Bilateral Supernumerary	165	1.025	2.45	15.79	97	5.431	10.39	55.00
Rib Unilateral Supernumerary :	152	0.676	1.43	7.27	102	5.512	11.98	55.00
Rib Wavy :	53	0.445	0.72	3.30	45	2.781	4.15	21.40
Sacral Centra/Arch Agenesis :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Sacral Centra/Arch Bipartite	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Sacral Centra/Arch Dumbbell :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Sacral Centra/Arch Fused :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Sacral Centra/Arch Hemicentra :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Sacral Centra/Arch Hypoplastic :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Sacral Centra/Arch Misaligned	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Sacral Centra/Arch Misshapen :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Sacral Centra/Arch Supernum.	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Squamosal Any Alteration :		0.008	0.07	0.63		0.064	0.55	4.80
Sternebra Fused	4	0.016	0.10	0.78	3	0.171	1.08	8.30
Sternebra Misaligned :	13	0.068	0.26	1.72	10	0.548	2.10	15.40
Sternebra Misshapen :	131	0.738	2.73	14.50	72	4.272	15.57	72.00
Sternebra Split :	8	0.051	0.19	1.14	8	0.475	1.86	13.00
Sternebral Agenesis :	90	0.973	8.37	72.00	16	1.081	9.30	80.00
Sternebral Extra Ossification Site :		0.006	0.06	0.48		0.059	0.51	4.40
Supraoccipital Bipartite :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Supraoccipital Hypoplastic :	4	0.038	0.21	1.60	4	0.255	1.36	10.00
Supraoccipital Misshapen :	2	0.018	0.16	1.37	2	0.116	1.00	8.70
Thoracic Centra/Arch Agenesis :	51	0.491	3.02	21.60	17	1.096	7.04	55.00
Thoracic Centra/Arch Bipartite	220	1.185	1.82	10.70	139	7.984	12.53	75.00
Thoracic Centra/Arch Dumbbell :	246	0.812	3.92	27.94	63	3.203	I1.85	76.90
Thoracic Centra/Arch Fused	1	0.007	0.06	0.50	1	0.053	0.46	4.00
Thoracic Centra/Arch Hemicentra:	3	0.012	0.06	0.35	3	0.173	0.86	5.00
Thoracic Centra/Arch Hypoplastic:	2	0.015	0.09	0.63	2	0.117	0.72	4.80
Thoracic Centra/Arch Misaligned :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Thoracic Centra/Arch Misshapen :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Thoracic Centra/Arch Supernum. :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Tibia Bowed :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Tibia Hypoplastic :		0.008	0.07	0.59	1	0.060	0.52	4.50
Tibia Misshapen	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Tympanic annulus Any Alteration :		0.008	0.07	0.63		0.064	0.55	4.80
Ulna Hypoplastic :		0.008	0.07	0.59		0.060	0.52	4.50
Ulna Misshapen	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Vertebral Count Alteration :	15	0.112	0.39	2.43	13	0.753	2.51	13.00
Vomer Any Alteration :	0	0.000	0.00	0.00	0	0.000	0.00	0.00

TABLE 12

SKELETAL ALTERATIONS IN CrI:CD®(SD)BR RATS

GESTATION DAY 21

Total studies: 97
Total litters: 2.094
Total fetuses: 14.364

	FETAL INCIDENCE				LITTER INCIDENCE			
	No.	**Avg(%)**	**S.D.**	**Max**	**No.**	**Avg(%)**	**S.D.**	**Max**
Abasophalangy :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Acrania :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Alisphenoid Any Alteration :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Amesophalangy :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Aphalangy :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Atelephalangy :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Atlas Bipartite :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Atlas Hypoplastic :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Basioccipital Any Alteration :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Basisphenoid Misshapen :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Cervical Centra/Arch Agenesis		0.008	0.06	0.48		0.073	0.56	4.30
Cervical Centra/Arch Bipartite	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Cervical Centra/Arch Dumbbell :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Cervical Centra/Arch Fused	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Cervical Centra/Arch Hemicentra	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Cervical Centra/Arch Hypoplastic	4	0.027	0.21	1.58	2	0.141	1.08	8.30
Cervical Centra/Arch Misaligned	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Cervical Centra/Arch Misshapen :	2	0.017	0.10	0.71	2	0.158	0.85	5.00
Cervical Centra/Arch Supernum. :		0.008	0.06	0.49	1	0.085	0.65	5.00
Clavicle/Scapula Agenesis :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Clavicle/Scapula Elongated	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Clavicle/Scapula Hypoplastic :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Clavicle/Scapula Misshapen	3	0.031	0.20	1.55	3	0.251	1.43	10.00
Craniostenosis :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Exoccipital Any Alteration :	1	0.012	0.09	0.71	1	0.085	0.65	5.00
Femur Bowed :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Femur Hypoplastic	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Femur Misshapen :		0.005	0.03	0.27	1	0.078	0.60	4.60
Fibula Bowed :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Fibula Hypoplastic :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Fibula Misshapen :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Fontanel Enlarged :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Frontal Bone island	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Frontal Fused :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Frontal Hypoplastic	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Frontal Misshapen :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Humerus Hypoplastic :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Humerus Misshapen :		0.005	0.04	0.30	1	0.081	0.62	4.80
Hyoid Bone Agenesis :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Hyoid Bone Hypoplasic :	9	0.067	0.36	2.31	8	0.619	2.80	16.70
Hyoid Bone Misshapen :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Ilium/Ischium/Pubis Agenesis :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Ilium/Ischium/Pubis Elongated :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
ilium/Ischium/Pubis Hypoplastic :	1	0.011	0.08	0.64	1	0.100	0.77	5.90
Ilium/Ischium/Pubis Misaligned	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Ilium/Ischium/Pubis Misshapen	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Ilium/Ischium/Pubis Thickened	0	0.000	0.00	0.00	0	0.000	0.00	0.00

	FETAL INCIDENCE				LITTER INCIDENCE			
	No.	Avg(%)	S.D.	Max	No.	Avg(%)	S.D.	Max
Interparietal Bipartite :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Interparietal Bone island :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Interparietal Fused :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Interparietal Hypoplastic :	18	0.196	0.48	1.58	18	1.824	4.5I	16.70
Lumbar Centra/Arch Agenesis :	3	0.015	0.07	0.37	3	0.244	1.07	5.60
Lumbar Centra/Arch Bipartite :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Lumbar Centra/Arch Dumbbell :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Lumbar Centra/Arch Fused :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Lumbar Centra/Arch Hemicentra :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Lumbar Centra/Arch Hypoplastic :	2	0.016	0.13	0.97	2	0.169	1.30	10.00
Lumbar Centra/Arch Misaligned :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Lumbar Centra/Arch Misshapen :	5	0.023	0.10	0.54	5	0.385	1.71	9.10
Lumbar Centra/Arch Supernum.:	1	0.005	0.04	0.27	1	0.068	0.52	4.00
Malar (=Zygomatic) Any Alter. :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Mandible Agenesis :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Mandible Hypoplastic :	2	0.020	0.11	0.70	2	0.147	0.80	5.00
Mandible Misshapen :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Maxilla Agenesis :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Maxilla Hypoplastic :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Maxilla Misshapen :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Metacarpus/Metatarsus Agen. :	2	0.018	0.14	1.06	2	0.147	1.13	8.70
Metacarpus/Metatarsus Hypopl.:	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Multiple skull bone alterations :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Nasal Bone island :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Nasal Fused :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Nasal Hypoplastic :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Nasal Misshapen :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Palatine Any Alteration :	1	0.009	0.07	0.56	1	0.095	0.73	5.60
Parietal Agenesis :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Parietal Bone island :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Parietal Fused :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Parietal Hypoplastic :	6	0.061	0.23	1.34	6	0.622	2.25	12.50
Parietal Misshapen :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Phalanx Agenesis :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Phalanx Fused :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Phalanx Misaligned :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Phalanx Supernumerary :	1	0.007	0.05	0.40	1	0.044	0.34	2.60
Premaxilla Any Alteration :	1	0.009	0.07	0.56	1	0.095	0.73	5.60
Presphenoid Any Alteration :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Radius Hypoplastic :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Radius Misshapen :	1	0.005	0.04	0.30	1	0.081	0.62	4.80
Rib Agenesis :	2	0.009	0.05	0.28	2	0.149	0.81	4.80
Rib Branched :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Rib Cervical-bilateral :	25	0.228	0.64	4.10	20	1.547	3.27	13.00
Rib Cervical-unilateral :	63	0.372	0.52	1.94	46	3.543	4.42	15.00
Rib Clubbed :	22	0.224	0.96	6.58	14	1.368	5.21	27.80
Rib Discontinuous :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Rib Fused :	3	0.016	0.09	0.67	2	0.141	0.76	4.30
Rib Hypoplastic :	17	0.082	0.24	1.40	15	1.175	3.02	14.30
Rib Intercostal :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Rib Knobby :	15	0.147	0.46	2.51	12	0.815	2.47	10.50
Rib Misaligned :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Rib Misshapen :	6	0.027	0.21	1.60	1	0.068	0.52	4.00
Rib Thickened :	3	0.036	0.21	1.48	3	0.307	1.77	12.50

	FETAL INCIDENCE				LITTER INCIDENCE			
	No.	Avg(%)	S.D.	Max	No.	Avg(%)	S.D.	Max
Rib Bilateral Supernumerary :	457	3.078	4.31	22.94	223	19.66	22.5	85.70
Rib Unilateral Supernumerary :	597	3.665	4.67	17.26	275	23.26	27.6	86.40
Rib Wavy :	37	0.320	0.61	2.11	24	2.109	3.58	11.80
Sacral Centra/Arch Agenesis :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Sacral Centra/Arch Bipartite :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Sacral Centra/Arch Dumbbell :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Sacral Centra/Arch Fused :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Sacral Centra/Arch Hemicentra :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Sacral Centra/Arch Hypoplastic :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Sacral Centra/Arch Misaligned :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Sacral Centra/Arch Misshapen :	17	0.089	0.22	1.00	14	1.164	2.82	12.00
Sacral Centra/Arch Supernum.:	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Squamosal Any Alteration :	3	0.035	0.16	0.95	3	0.298	1.31	6.70
Sternebra Fused :	9	0.067	0.22	1.30	7	0.563	1.57	6.30
Sternebra Misaligned :	13	0.101	0.27	1.36	13	1.244	3.27	20.00
Sternebra Misshapen :	138	1.289	3.52	16.20	85	6.042	15.49	69.60
Sternebra Split :	4	0.038	0.15	0.89	4	0.337	1.28	6.30
Sternebral Agenesis :	6	0.052	0.40	3.05	4	0.295	2.26	17.39
Sternebral Extra Ossification Site :	1	0.007	0.05	0.39	1	0.071	0.55	4.20
Supraoccipital Bipartite :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Supraoccipital Hypoplastic :	11	0.110	0.33	1.43	11	1.069	3.19	14.30
Supraoccipital Misshapen :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Thoracic Centra/Arch Agenesis :	7	0.052	0.26	1.90	5	0.420	1.45	7.70
Thoracic Centra/Arch Bipartite :	24	0.211	0.43	1.94	23	1.844	3.92	20.00
Thoracic Centra/Arch Dumbbell :	13	0.109	0.39	2.24	13	1.036	3.51	19.20
Thoracic Centra/Arch Fused :	2	0.009	0.05	0.27	2	0.139	0.75	4.20
Thoracic Centra/Arch Hemicentra:	1	0.005	0.04	0.29	1	0.076	0.59	4.50
Thoracic Centra/Arch Hypoplastic:	4	0.042	0.22	1.57	4	0.400	1.96	13.30
Thoracic Centra/Arch Misaligned :	2	0.009	0.05	0.29	2	0.141	0.76	4.30
Thoracic Centra/Arch Misshapen :	43	0.436	1.02	6.31	37	3.351	6.56	33.30
Thoracic Centra/Arch Supernum.:	5	0.036	0.27	2.10	3	0.392	3.01	23.10
Tibia Bowed :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Tibia Hypoplastic :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Tibia Misshapen :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Tympanic annulus Any Alteration :	1	0.009	0.07	0.56	1	0.095	0.73	5.60
Ulna Hypoplastic :	0	0.000	0.00	0.00	0	0.000	0.00	0.00
Ulna Misshapen :	1	0.005	0.04	0.30	1	0.081	0.62	4.80
Vertebral Count Alteration :	44	0.360	0.67	3.03	29	2.742	**4.88**	17.60
Vomer Any Alteration :	0	0.000	0.00	0.00	0	0.000	0.00	0.00

FIGURE 1
AVERAGE FETAL WEIGHT ON GESTATION DAY 20
BY CRL PRODUCTION SITE

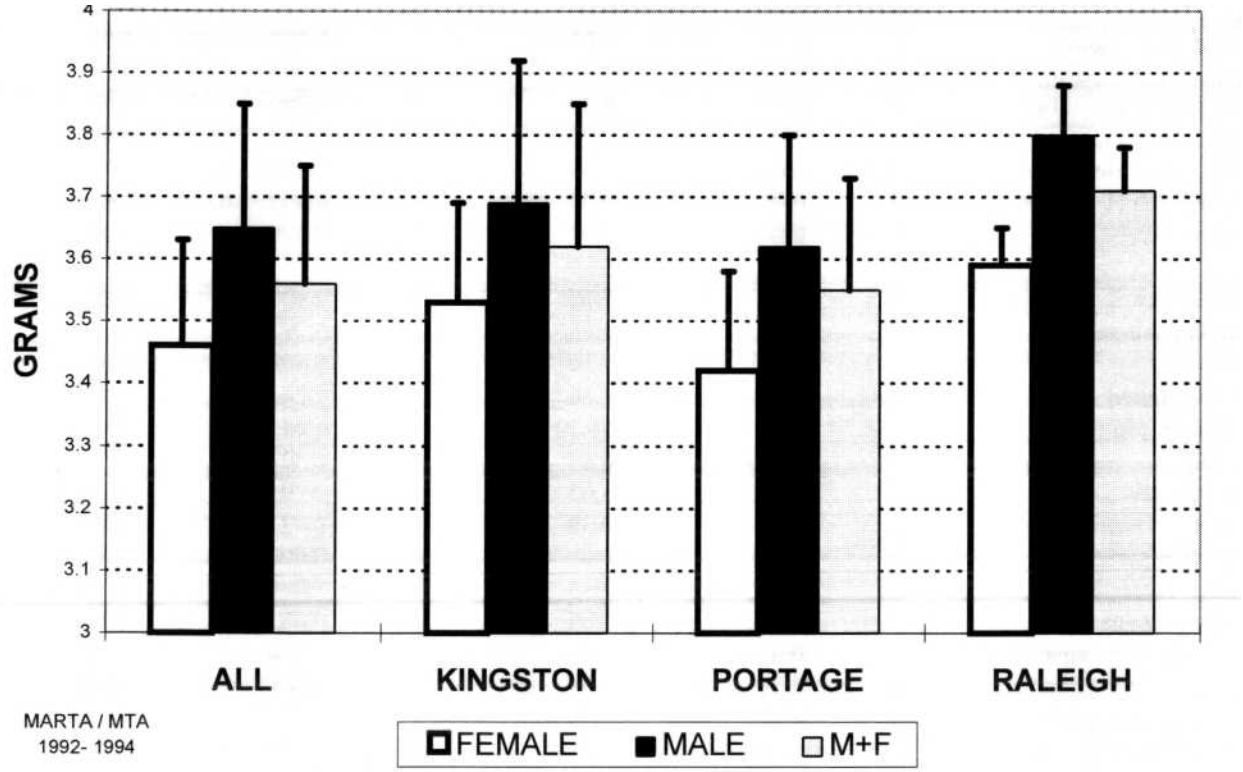

FIGURE 2
AVERAGE FETAL WEIGHT ON GESTATION DAY 21
BY CRL PRODUCTION SITE

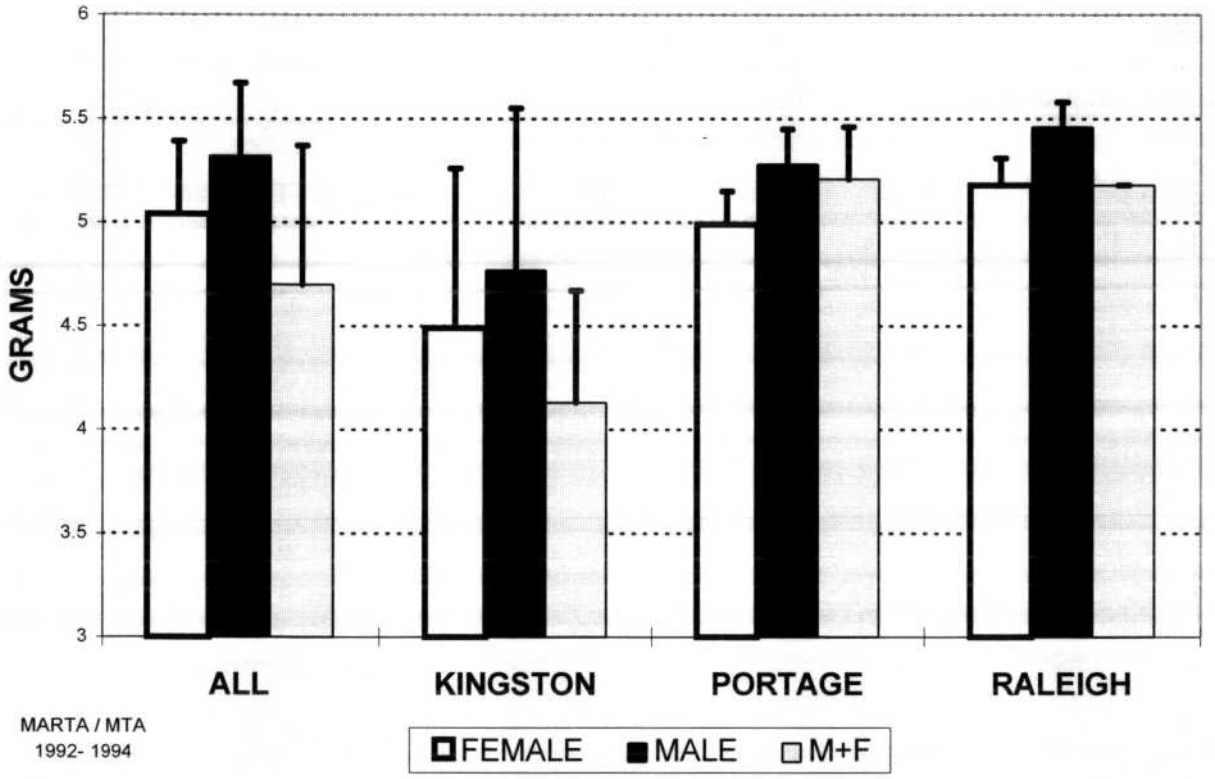

FIGURE 3
AVERAGE FETAL WEIGHT OF CrI:CD®(SD)BR RATS
ON GESTATION DAY 20 BY COMPANY

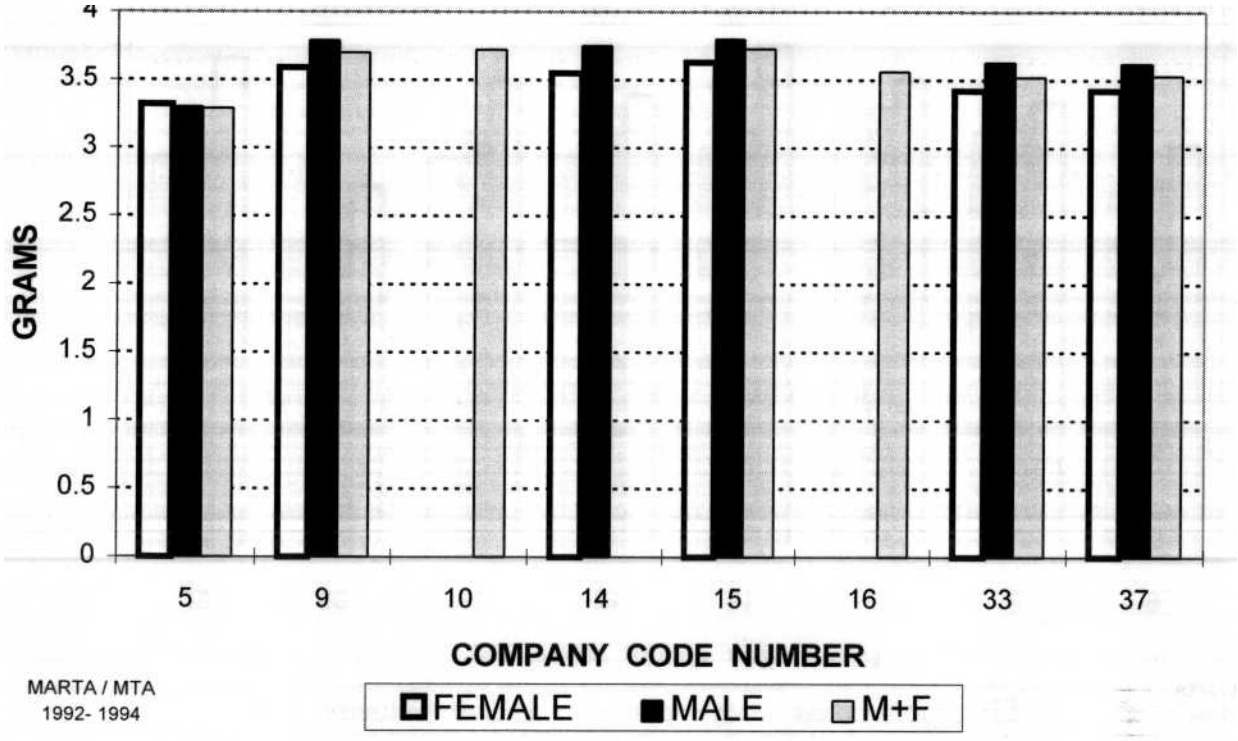

FIGURE 4
AVERAGE FETAL WEIGHT OF CrI:CD®(SD)BR RATS
ON GESTATION DAY 21 BY COMPANY

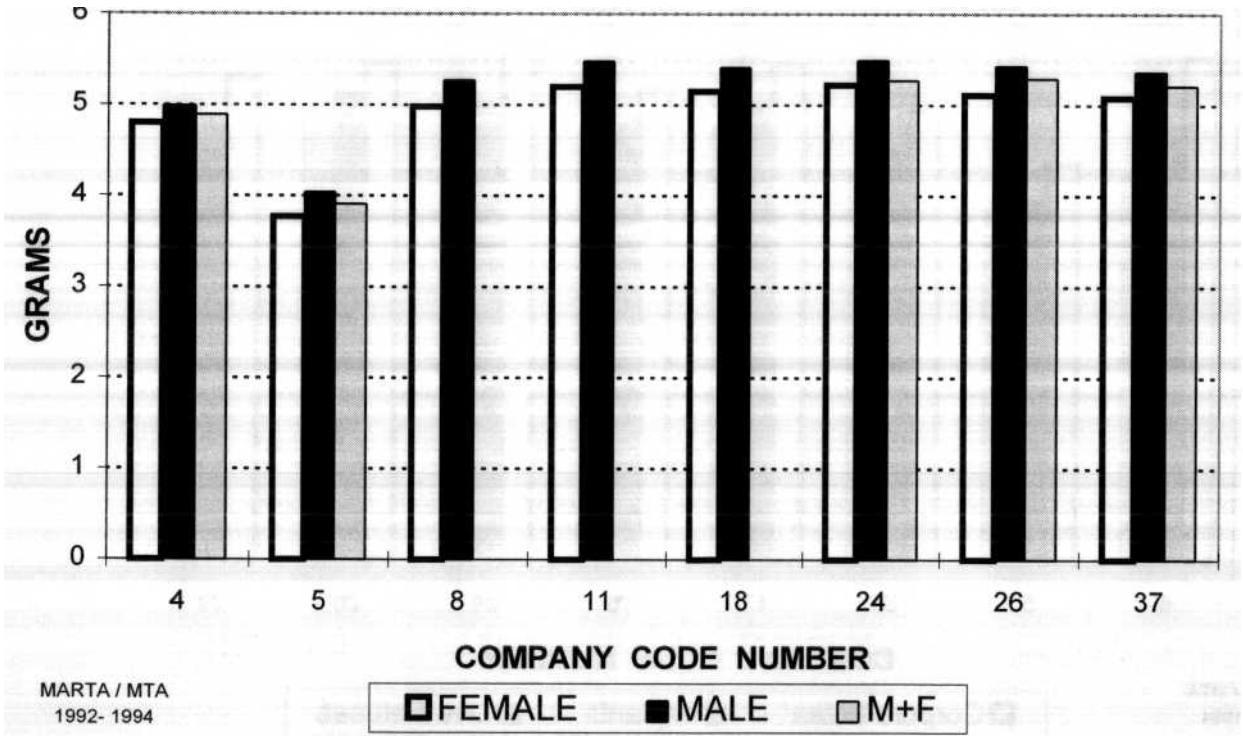

FIGURE 5
LITTER PARAMETERS OF CrI:CD®(SD)BR RATS
ON GESTATION DAY 20 BY COMPANY

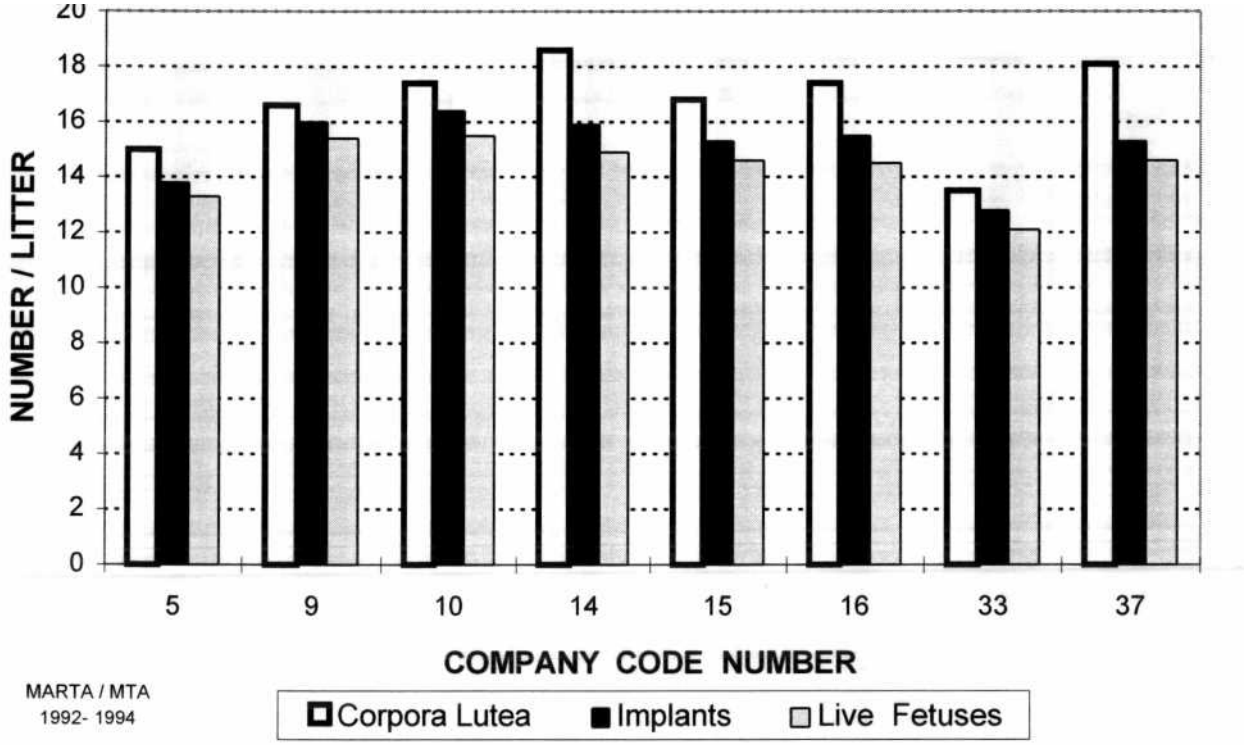

FIGURE 6
LITTER PARAMETERS OF CrI:CD®(SD)BR RATS
ON GESTATION DAY 21 BY COMPANY

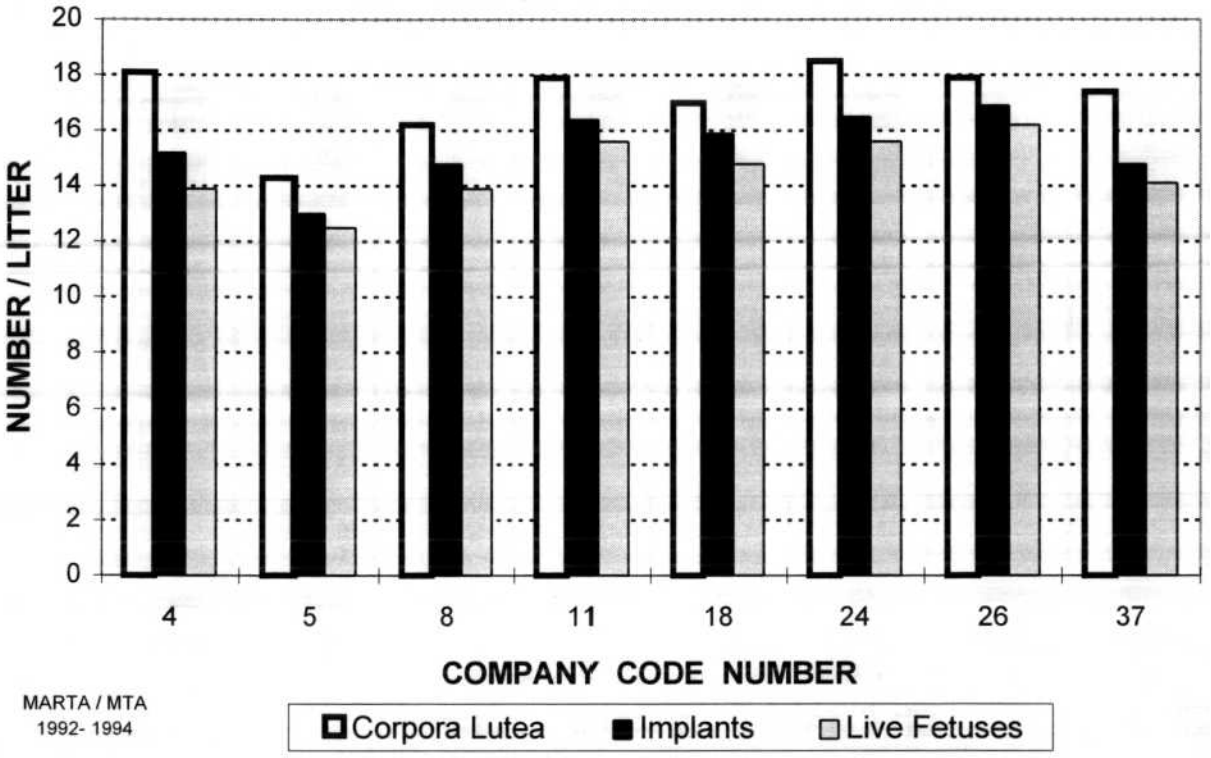

FIGURE 7
AVERAGE BIRTH WEIGHT OF CrI:CD®(SD)BR RATS
BY CRL PRODUCTION SITE

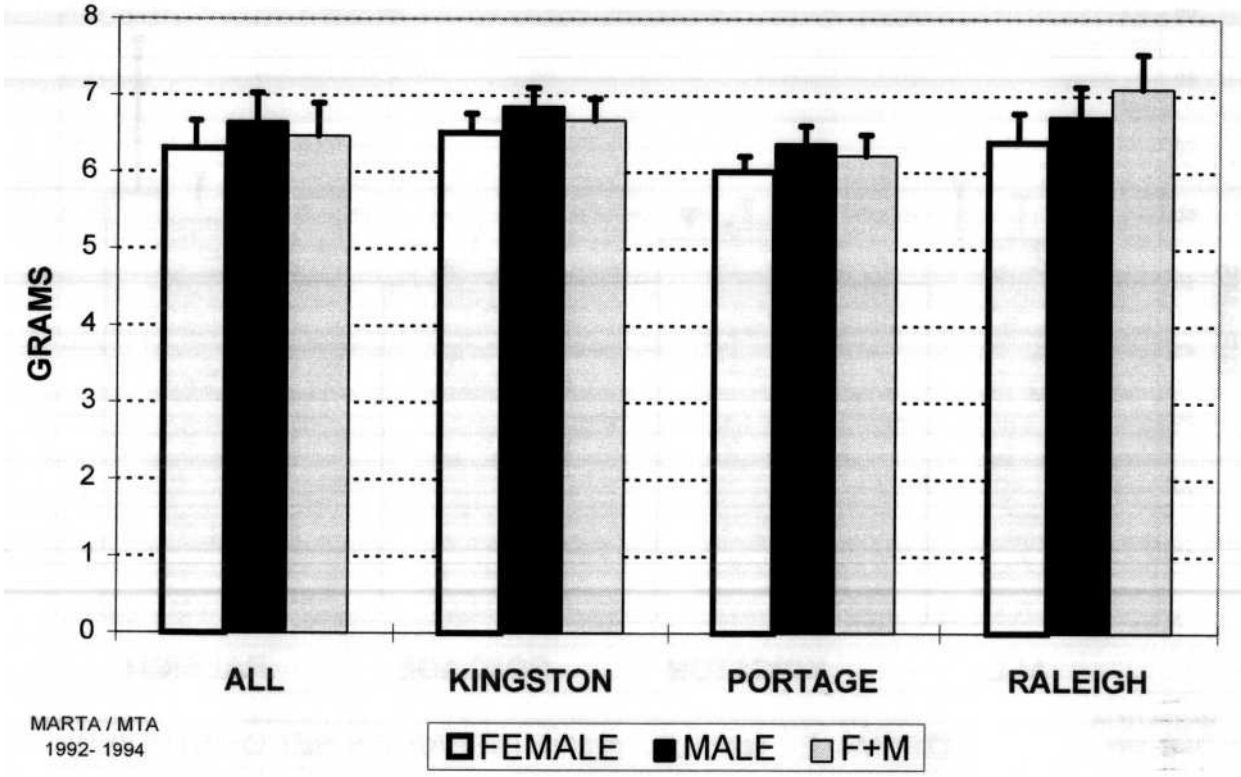

FIGURE 8
AVERAGE IMPLANTS AND LIVE PUPS AT BIRTH
BY COMPANY

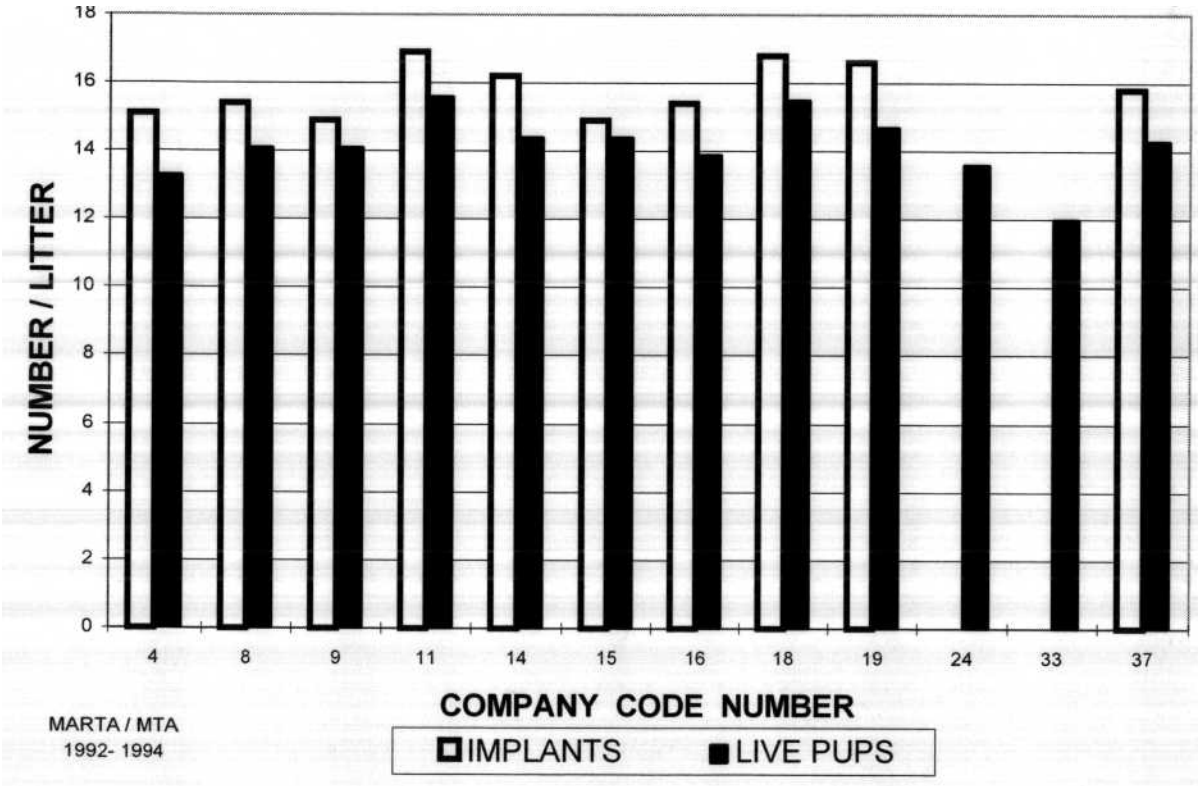

FIGURE 9
AVERAGE POSTNATAL DAY 21 PUP WEIGHT